

# EXHIBIT T

IN THE UNITED STATES DISTRICT COURT  
MIDDLE DISTRICT OF TENNESSEE  
AT NASHVILLE

STATE FARM FIRE AND CASUALTY )  
COMPANY, )  
)  
Plaintiff, )  
)  
v. )  
)  
SPECIALTY SURGERY CENTER, PLLC, )  
KENNETH R. LISTER, M.D., ELIZABETH )  
BRAY, PEGGY B. BUMGARNER, ROGER )  
D. BUMGARNER, WILMA S. CARTER, )  
LAWRENCE CARTER, JUDY COLLINS, )  
WANDA J. COX, PERRY COX, WANDA )  
J. DINGESS, BOBBY A. FOSTER, )  
DOROTHY A. FUELLING, RICHARD E. )  
FUELLING, CRAIG E. WEAVER, )  
Administrator Ad Litem of the Estate of )  
PATRICIA A. GAMBACCINI, DANETTE )  
GRAHAM, GEORGEANNE HUBBARD, )  
LINDA JACKSON, JOHN JOHNSON, EDNA )  
S. KEYES, WILLIAM LAPISKA, SHERRY A. )  
MCDAVID, next of kin of DONALD F. )  
MCDAVID, DARWIN L. NEALON, )  
Administrator of the Estate of DALLAS RAY )  
NEALON, JOCELYN KAE NORRIS, JAMES )  
PALMER, MICHELLE PALMER, WANDA )  
L. REED, J.E. REED, JANICE K. RHIND, )  
CHRISTOPHER G. RHIND, SHIRLEY )  
SAVERCOOL, PAULA K. SMITH, JIM F. )  
SMITH, and DALE WILLIS, )  
)  
Defendants. )

Case No. 2:15-cv-00026

Chief Dist. Judge Kevin Sharp

Magistrate Judge Joe Brown

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ORDER CERTIFYING QUESTIONS OF LAW TO TENNESSEE SUPREME COURT  
UNDER TENNESSEE SUPREME COURT RULE 23

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The United States District Court for the Middle District of Tennessee certifies the following questions to the Supreme Court of Tennessee under Tennessee Supreme Court Rule 23.

**(A) The style of the case**

The style of the case is in the caption of this Order.

**(B) A statement of facts showing the nature of the case, the circumstances out of which the questions of law arise, the questions of law to be answered, and any other information the certifying court deems relevant to the questions of law to be answered.**

**1. Nature of the case**

**General background**

The unresolved Tennessee state law issues for the Tennessee Supreme Court's consideration arise from claims asserted in underlying tort litigation related to the 2012 fungal meningitis outbreak. In this declaratory judgment action, the Insurer (State Farm) sues the Insureds (Specialty Surgery Center, PLLC and Kenneth Lister, MD) and former patients ("Individual Tort Victim Defendants" or "ITV Defendants"). The Insurer seeks a declaration that it does not owe the Insureds a defense or indemnity coverage in the tort suits brought by the ITV Defendants against the Insureds.

The ITV Defendants are former patients of the Insured health care providers asserting injuries from the 2012 fungal meningitis outbreak. These lawsuits, along with scores of others against health care providers around the country, have been consolidated in multi-district litigation in the United States District Court for the District of Massachusetts.<sup>1</sup> One of the claims the ITV Defendants make against Dr. Lister and Specialty Surgery Center (“SSC”) in the underlying tort suits is that the Insured health care providers are strictly liable under Tennessee’s Product Liability Act, Tennessee Code Annotated § 29-28-101, *et seq.*, as “sellers” of contaminated medication furnished to the ITV Defendants as a component of health care services.

#### **Insurer’s position in declaratory judgment action**

State Farm’s position is two-fold: First, the ITV Defendants cannot, as a matter of law, maintain a cause of action for product liability against SSC or Dr. Lister related to the outbreak. Second, if the Court rules that the product liability claim is not viable as a matter of law, the only remaining viable claims against SSC and Dr. Lister in the underlying tort suits are for professional health care liability, specifically excluded from coverage under the applicable insurance policy.<sup>2</sup>

State Farm requests that the Middle District of Tennessee declare that (1) the ITV Defendants cannot, as a matter of law, pursue a claim of strict product liability against the Insureds arising from the fungal meningitis outbreak; and (2) because the product liability claim is not legally viable, State Farm has no duty to provide a defense or indemnity coverage to the Insureds.

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<sup>1</sup> U.S. District Court, Massachusetts, MDL No. 2419 // Dkt. No 1:13-md-2419 (RWZ).

<sup>2</sup> This coverage suit hinges on the viability of the ITV Defendants’ product liability claim against SSC and Dr. Lister. If it is not viable, State Farm’s policy does not cover the claims.

## 2. Circumstances out of which the questions of law arise

In the summer 2012, New England Compounding Center (“NECC”) – a compounding pharmacy in Massachusetts – produced three batches of preservative-free methylprednisolone acetate (“MPA”). During production, the MPA was contaminated with a fungus. NECC shipped contaminated vials to health care providers across the country, including three (3) clinics in Tennessee, one of which was SSC.

Dr. Lister and other physicians across the country injected the MPA supplied by NECC in individual, sealed vials, during procedures known as epidural steroid injections (“ESIs”), unaware that the MPA was contaminated. Hundreds of patients in multiple states filed suit. Twenty-four (24) lawsuits were filed against SSC and Dr. Lister. All the federal fungal meningitis lawsuits, including those against SSC and Dr. Lister, have been consolidated for pretrial proceedings in multi-district litigation pending in the U.S. District Court for the District of Massachusetts.

NECC (the manufacturer of the medicine) filed a petition in bankruptcy in U.S. Bankruptcy Court on December 21, 2012. The Tennessee Product Liability Act of 1978 permits plaintiffs to pursue a claim for strict liability in tort against the seller in the chain of distribution of a good in only limited circumstances, including when the manufacturer is bankrupt.<sup>3</sup> In the underlying complaints against SSC and Dr. Lister, the ITV Defendants assert that SSC and Dr. Lister acted as “sellers” of the MPA for purposes of the Tennessee Product Liability Act when Dr. Lister injected the medicine into the ITV Defendants in 2012.<sup>4</sup> SSC and Dr. Lister dispute that they “sold” the medication and

<sup>3</sup> TENN. CODE ANN. §§ 29-28-102, -106.

<sup>4</sup> SSC and Dr. Lister moved to dismiss the product claims. The Massachusetts District Court denied the motion but noted on several occasions that there is no Tennessee law addressing whether a health care provider can be considered a seller of medication used incidental to health care services, exposing the

instead assert they used it only incidental to the delivery of professional health care services.

State Farm issued a commercial liability policy and a commercial liability umbrella policy to SSC and Dr. Lister that were in effect at the time of the injections in 2012. The parties agree that there is no specific exclusion in State Farm's policy for claims grounded in "strict product liability" against SSC and Dr. Lister. However, State Farm asserts that the product liability claim is not viable as a matter of law, and, if the product liability claim in the underlying complaints is not viable, State Farm should not be obligated to provide a defense and coverage.<sup>5</sup>

State Farm and the Insured health care providers aver that the ITV Defendants cannot maintain a strict product liability cause of action for two (2) principal reasons. First, they assert that the claims against the Insureds are health care liability actions governed by Tennessee's Health Care Liability Act ("HCLA")<sup>6</sup>, which is the ITV Defendants' exclusive substantive remedy on these facts. Second, they assert that SSC was not acting as a "seller" under Tennessee's Product Liability Act.<sup>7</sup>

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health care provider to strict product liability. See Order on Global Motion to Dismiss, August 29, 2014, 2014 WL 4322409, at \*14-\*15 ("The Tennessee Clinic Defendants acknowledge that Tennessee has not specifically addressed whether health care providers can be held strictly liable as sellers...This court's case law research did not unearth any Tennessee cases in which products liability claims were successfully brought against health care providers, nor any cases indicating that health care providers were categorically not sellers or could not be sued under the [Tennessee Product Liability Act]....As of the date of this opinion, there are no cases dealing with the interaction of products liability claims with the [Tennessee Health Care Liability Act]").

<sup>5</sup> An answer on the issue of the viability of the product liability claim will resolve all (or virtually all) of the issues in the declaratory judgment action in front of this Court. In the MDL, the Intervenor Plaintiffs (Plaintiffs with suits against another Tennessee clinic who purchased and administered MPA from NECC, Saint Thomas Outpatient Neurosurgical Center, LLC) have moved for summary judgment on the same issue. Thus, in addition to resolving the issues in the declaratory judgment action, answering this question will likely resolve the same issue in the MDL.

<sup>6</sup> TENN. CODE ANN. § 29-26-101, *et seq.*

<sup>7</sup> TENN. CODE ANN. § 29-28-101, *et seq.*

### 3. Operative undisputed facts

The following material facts are undisputed for purposes of deciding these legal questions:

1. This declaratory judgment action follows tort lawsuits arising from the 2012 outbreak of fungal meningitis and fungal infection caused by three (3) batches of preservative-free methylprednisolone acetate compounded and sold by NECC from May 2012 through September 2012.

2. NECC was a compounding pharmacy located in Massachusetts. It was licensed as a pharmacy in Massachusetts, in Tennessee pursuant to Title 63 of the Tennessee Code, and in every other state in the union.

3. MPA is a steroid commonly used to treat chronic back or neck pain. During an epidural steroid injection, the MPA is injected into the epidural space with x-ray guidance. The medication reduces swelling and inflammation of the nerves and tissue surrounding the spine, relieving pain.

4. In 2012, SSC was an accredited ambulatory surgery center in Crossville, Tennessee, licensed pursuant to Title 68 of the Tennessee Code.<sup>8</sup>

5. Dr. Lister is an anesthesiologist licensed pursuant to Title 63 of the Tennessee Code. He was a member of SSC in 2012.

6. The ITV Defendants sought treatment for back and neck pain from SSC and Dr. Lister.

7. SSC procured MPA from NECC for Dr. Lister to use at SSC when treating patients.

8. SSC began purchasing MPA from NECC in July 2012 after Dr. Lister became concerned about possible adverse patient reactions from preservatives present in the brand-name version of the medication, "Depo Medrol," available commercially from Pfizer. SSC's Director of Nursing, Jean Atkinson, RN, in consultation with Dr. Lister and SSC's management company, made the decision to purchase a preservative-free formulation of MPA from NECC.

9. SSC paid NECC \$8.00 per one milliliter vial of MPA. Dr. Lister administered one vial of MPA to a patient during an epidural steroid injection.

10. Dr. Lister performed epidural steroid injections on the ITV Defendants to treat their back and neck pain. The steroid administered during the ITV Defendants' procedures was preservative-free MPA compounded by NECC.

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<sup>8</sup> SSC is no longer operating.

11. Two fees were charged for the epidural steroid injections: a physician fee by Dr. Lister, and a facility fee by SSC.

12. Dr. Lister charged the ITV Defendants and/or their insurers the physician fee for his professional services during the epidural steroid injection procedures.

13. SSC charged the ITV Defendants and/or their insurers a facility fee of \$1,250, which was a single, global fee for the epidural steroid injections that covered all aspects of the injection. This included:

a. The professional services of a nurse to assist Dr. Lister in performing the procedure, including administering a sedative when necessary<sup>9</sup>;

b. The professional services of a surgical technician to assist Dr. Lister in performing the procedure, including positioning the fluoroscopy (x-ray) machine used to provide Dr. Lister with real-time images of the patient's spine during the procedure to ensure the MPA was being injected into the epidural space;

c. Use of SSC's facility, including an operating room for the procedure and a post-procedure recovery room;

d. Use of SSC's medical equipment, including the fluoroscopy machine used during the procedure and the equipment used to monitor the ITV Defendants' vital signs during the procedure;

e. The medications administered during the procedure, including, but not limited to, MPA from NECC;

f. The medical supplies used during the procedures, such as latex gloves, surgical masks, and gowns; and,

g. Administrative services such as recordkeeping, billing, and scheduling.

14. SSC was reimbursed approximately \$200-\$300 for the ITV Defendants' procedures.<sup>10</sup>

15. The majority of the ITV Defendants are Medicare beneficiaries.

16. Neither SSC nor Dr. Lister billed the ITV Defendants or their insurers separately for the MPA administered during their procedures.

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<sup>9</sup> Some patients chose not to be sedated because they wanted to be able to drive home after the procedure and could not do so if they had been sedated.

<sup>10</sup> The reimbursement varied to some extent depending on the terms of the contract between SSC and the patient's insurer.



17. SSC and Dr. Lister did not collect sales tax from the ITV Defendants or their insurers for the MPA administered during the procedures.

18. The steroid administered to the ITV Defendants was later found to have been contaminated during compounding by NECC.

19. The ITV Defendants allege that the steroid caused varying degrees of injury and, in some cases, death.

20. NECC sought bankruptcy protection on December 21, 2012.

21. After NECC declared bankruptcy, the ITV Defendants filed suit against SSC and Dr. Lister alleging, among other things, that they are strictly liable as “sellers” of the MPA administered to the ITV Defendants, under Tenn. Code Ann. § 29-28-106.

22. NECC’s bankruptcy plan was confirmed on May 20, 2015. The plan includes a settlement fund of approximately \$200 million for the benefit of the victims of NECC’s wrongdoing. The lawsuits against various clinics continue, including those against SSC and Dr. Lister.

#### **4. Questions of law to be answered**

The District Court requests that the Tennessee Supreme Court answer the following questions:

- (1) Can a patient maintain a strict products liability action against an ambulatory surgery center licensed under Tennessee Code Title 68, or a physician licensed under Tennessee Code Title 63, for an injury sustained during an epidural steroid injection procedure, given the definition of a “health care liability action” under Tenn. Code Ann. § 29-26-101 and the burden of proof requirements established by Tenn. Code Ann. § 29-26-115?
- (2) Is an ambulatory surgery center, licensed pursuant to Tennessee Code Title 68, “engaged in the business of selling” the steroid administered during an epidural steroid injection procedure, so as to be strictly liable as a “seller” under Tenn. Code Ann. § 29-28-106?

#### **5. Any other information the certifying court deems relevant to the questions of law to be answered**

None.

**(C) The names of each of the parties**

The parties are identified in the style above.

**(D) The names, addresses, and telephone numbers of counsel for each party**

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*Attorneys for Defendants SSC and Dr. Lister*

**(E) A designation of the moving parties**

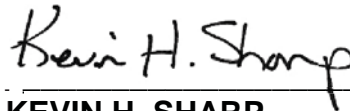
The Court designates the following as the moving parties:

- State Farm Fire & Casualty Company
- Specialty Surgery Center, PLLC
- Kenneth Lister, MD.<sup>11</sup>

\* \* \* \* \*

This honorable Court hereby certifies the above questions by this Order to the Tennessee Supreme Court and requests that the Tennessee Supreme Court consider them and answer them in due course.

Dated: June 16, 2016



**KEVIN H. SHARP  
CHIEF DISTRICT JUDGE  
UNITED STATES DISTRICT COURT  
MIDDLE DISTRICT OF TENNESSEE**

<sup>11</sup> Given that State Farm, SSC, and Dr. Lister's interests align on the questions presented, this Court designates them as the moving parties, and respectfully recommends that they file the opening brief(s), and that the other parties to this action file the response brief. If the Tennessee Supreme Court prefers that only one party be designated, this Court suggests that State Farm be designated as the moving party.

Jointly submitted for entry,

**GIDEON, COOPER & ESSARY, PLC**

*/s/ Chris J. Tardio*

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